- 14. (Original) A method of doing business, comprising selling nasal CPAP seals in a plurality of differing sizes.
- 5 15. (Original) The method of claim 14 wherein said plurality of differing sizes includes a number of sizes adapted to fit infant faces.
- 16. (Original) The method of claim 14 wherein said plurality of differing sizes are adapted to fit a plurality of cannulae, in differing sizes.

15 REMARKS

ALLOWED CLAIMS

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Applicant notes with gratitude the allowance of claims 1-4.

20 CLAIM REJECTIONS UNDER 35 USC §102

Claims 5, 9, 10 and 12 stand rejected under 35 USC \$102 as being anticipated by U.S. Patent 6,328,038 issued to Kessler ("Kessler"). Amended claim 5 recites that in an unfolded state, said nose covering region abuts each of said pair of wings. This is certainly not the case for the device of Kessler, where central nose portion 24 and wing portion 25 do not abut each other at the putative cuts (parallel edges 24). Additionally, paragraph (a) of amended claim 5 clarifies the shape of the nose covering and the nostril apertures. The device of Kessler does not have nostril apertures that are sized and spaced apart so as to align with human infant nostrils.

Paragraph (a) of claim 9 also recites the features of the nose covering portion that are missing from Kessler.

Moreover, the recitation of the release liner is part of the genius of the achievement of the inventor, who has taken an item that was previously made to order by hospital personnel, and has created a product that can be mass produced and distributed. This relieves hospital personnel of a time-consuming task. Adding the release liner was part of this process, which all depended on the keen insight that the CPAP seals could be mass produced. Claims 10 and 12 are patentably distinct over the prior art because the depend on claim 9, which is so distinct.

CLAIM REJECTIONS UNDER 35 USC \$103

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Claims 6-8, 11 and 13-16 stand rejected under 35 USC \$103 as being unpatentable over Kessler. Paragraph (a) of amended claim 6 is distinguished over Kessler in the same way as is paragraph (a) of claim 5. Moreover, as noted in the specification at page 6, lines 17-32, making the seal semi-transparent is a deliberate choice that required the trade-off of accepting a clean, but not sterile, seal. Also, this was based on the recognition of the importance of visual inspection of the tissue under the CPAP seal. This represents an importance advance, because as noted in the cited text, the prior art CPAP seals, which were cut out of wound dressing, were opaque. Accordingly, the CPAP seal of claim 6 addresses a long felt need in the industry that had previously been left unaddressed. This was done through the insightful recognition that by mass producing the CPAP seals the added benefit of transparency could be realized, because unlike wound dressing, a CPAP seal is not required to be sterile.

Paragraph (a) of claim 8 is distinguished over
Kessler just as is paragraph (a) of claim 5. Moreover,
similar to the release liner of claim 9, the sanitary package
of claim 8 is part of the rendering of a previously made to

order item into a mass produced item, with all of the attendant benefits. Accordingly claim 8 is patentably distinct over the prior art.

With respect to claim 14, it is important to note 5 that Kessler does not disclose a nasal CPAP seal. No seal is created by Kessler's device. The method of selling the seals in a variety of sizes is one more aspect of the non-obvious innovation of mass producing and distributing that which has been heretofore made to order by hospital staff. For years, 10 hospital staff have struggled to produce infant nasal CPAP seals from wound dressing, when required. No doubt many infant injuries were caused by the opaque seals that resulted from the opaque wound dressing. Moreover, there has no doubt been a variation in the quality of made-to-order CPAP seals, 15 from the very good and well shaped, to the poorly shaped seal made by a nurse inexperienced in forming CPAP seals. Yet nobody thought to overcome these problems by mass producing CPAP seals and selling them in a variety of sizes. This step represents an important innovation that has benefited 20 doctors, nurses, hospitals and, most importantly of all, prematurely born infants. It deserves patent protection.

The remaining claims are patentable because each depends on a patentable base claim.

It is respectfully submitted that the claims are now in condition for allowance. Reconsideration and early notice of allowance are respectfully solicited.

Respectfully submitted,

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April Westfall